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10/785,327	02/24/2004	Paul J. Sheskey	63633	9686

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The Dow Chemical Company
P.O. BOX 1967
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EXAMINER	
HELM, CARALYNNE E	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,327	SHESKEY ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office action is a revision of, and supersedes, the Office action mailed February 19, 2010.

Election/Restrictions

To summarize the election of record, applicant elected Group I drawn to processes for dispersing fluids in a mass of solid particles.

Applicant is advised that should claim 27 be found allowable, claim 28 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 21 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7,070,828 (hereafter patent '828') as evidenced by Rudnic et al. (see below for citation). Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach a method where particles are agglomerated by being contacted with water-based air foam and then mixed. While the particle size recited by patent '828 is 1 mm to 25 mm and that of the instant claim is less than 1000 microns, routine experimentation by one of ordinary skill in the art based upon the teachings of patent '828 would render this limitation obvious. Patent '828 teaches cellulose esters and poly(vinylpyrrolidone) as the polymer included in the foam which are both known binders in the pharmaceutical art (see Rudnic et al. claim 8) and meet the limitation of the instantly claimed binder. Therefore claim 21 is obvious over claims 1-2 of U.S. Patent No. 7,070,828 as evidenced by Rudnic et al.

Claims 21-23 and 27-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7,070,828 (hereafter patent '828') in view of Hardie-Muncy et al. (see below for citation) as evidenced by Rudnic et al. Although the conflicting claims are not identical, they are

not patentably distinct from each other because both teach a method where particles are agglomerated by being contacted with water-based air foam and then mixed. While the particle size recited by patent '828 is 1 mm to 25 mm and that of the instant claim is less than 1000 microns, routine experimentation by one of ordinary skill in the art based upon the teachings of patent '828 would render this limitation obvious. Patent '828 teaches cellulose esters and poly(vinylpyrrolidone) as the polymer included in the foam which are both known binders in the pharmaceutical art (see Rudnic et al. claim 8) and meet the limitation of the instantly claimed binder. Patent '828 is silent regarding the atomization of the foam and whether it is applied on top of the particles.

Hardie-Muncy et al. teach the agglomeration of moisture sensitive particulate materials by whipping a coating medium into a foam then applying the foam to the (on top of without atomization) particles so as to agglomerate and protect them from exposure to moisture (see abstract and column 1 lines 5-11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the water-based air foam of Patent '828 on top of their claimed particles without atomization since Hardie-Muncy et al. teach this application procedure as known means for the agglomerating particles with a water-based air foam. Therefore claims 21-23 and 27-28 are obvious over claims 1-2 of U.S. Patent No. 7,070,828 in view of Hardie-Muncy et al. as evidenced by Rudnic et al.

Claims 21 and 24-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-9 of U.S. Patent No. 7,011,702 (hereafter patent '702) in view of Rudnic et al. and Baichwal et al. (US Patent

No. 5,773,025). Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach a method where particles are agglomerated by being contacted wit h water-based air foam and then mixed. While the particle size and presence of a therapeutic are not recited by the claims of patent '702, agglomerated particles containing a medicament are taught by Baichwal et al. (see claim 1). In addition, the particles utilize in these agglomerates are taught to be 10 μm or less (see column 11 lines 28-48). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the particles of Baichwal et al. in the method of patent '702 since both envisioned the production of an agglomerated final product. Patent '702 teaches cellulose esters as the polymer included in the foam which is a known binder in the pharmaceutical art (see Rudnic et al. claim 8) and meet the limitation of the instantly claimed binder. Therefore claims 21 and 24-25 is obvious over claims 8-9 of U.S. Patent No. 7,011,702.

Claims 21-25 and 27-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-9 of U.S. Patent No. 7,011,702 (hereafter patent '702) in view of Baichwal et al. and Hardie-Muncy et al. as evidenced by Rudnic et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach a method where particles are agglomerated by being contacted wit h water-based air foam and then mixed. While the particle size and presence of a therapeutic are not recited by the claims of patent '702, agglomerated particles containing a medicament are taught by Baichwal et al. (see claim 1). In addition, the particles utilize in these agglomerates are taught to be 10 μm

or less (see column 11 lines 28-48). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the particles of Baichwal et al. in the method of patent '702 since both envisioned the production of an agglomerated final product. Patent '702 teaches cellulose esters and poly(vinylpyrrolidone) as the polymer included in the foam which are both known binders in the pharmaceutical art (see Rudnic et al. claim 8) and meet the limitation of the instantly claimed binder. Patent '702 is silent regarding the atomization of the foam and whether it is applied on top of the particles.

Hardie-Muncy et al. teach the agglomeration of moisture sensitive particulate materials by whipping a coating medium into a foam then applying the foam to the (on top of without atomization) particles so as to agglomerate and protect them from exposure to moisture (see abstract and column 1 lines 5-11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the water-based air foam of Patent '828 on top of their claimed particles without atomization since Hardie-Muncy et al. teach this application procedure as known means for the agglomerating particles with a water-based air foam. Therefore claims 21-25 and 27-28 are obvious over claims 8-9 of U.S. Patent No. 7,011,702 in view of Baichwal et al. and Hardie-Muncy et al. as evidenced by Rudnic et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. (previously cited) in view of Lopez (previously cited), and as evidenced by Rudnic et al. (previously cited).

Parikh et al. teach the coating of drug containing particle cores that are 80 to 300 micrometers in size (see paragraph 34; instant claims 21 and 24-25). Parikh et al. go

on to teach both a taste masking and texture masking coating that are utilized in the invention (see paragraphs 20-21 and 35). This coating is also taught to cover the entire surface of the core (see paragraphs 32 and 35). An embodiment of a texture masking composition teaches an aqueous solvent in the form of ethanol and water that constitutes 90 wt% (as calculated by the examiner) of the coating preparation and also includes hydroxypropylmethylcellulose (see example 2). Rudnic et al. teach that hydroxypropylmethylcellulose was a known pharmaceutical binder (see claim 8; instant claim 21). The coating process is taught to occur in a fluidized bed or rotary coater (see paragraph 43). The resulting particles are a granular material. After production of these coated particles, Parikh et al. teach their transformation into larger granules (agglomeration) (see paragraph 56; instant claims 21). Thus at the end of the processing steps of Parikh et al., agglomerated particles are the result. These agglomerated particles are capable of being utilized in a dosage form since they contain a drug (see instant claim 21). Although Parikh et al. teach that several methods can be used to coat the particle cores, they do not teach coating by application of a foam (see paragraphs 43 and 52).

Lopez teaches a process of coating pharmaceutical solid forms (see column 1 lines 6-8). Lopez teaches that the process of coating solid forms by conventional means of dipping, pouring, or spraying often leads to unevenness in the coating layer (see column 1 lines 11-12 and 15-20). In addition, Lopez teaches that spray coating a liquid typically requires high pressures to appropriately atomize the coating medium and poses several challenges to uniform coating (see column 1 lines 46-75). The process taught by Lopez to circumvent the challenges of standard spray coating is amenable to

nearly any type of coating medium and results in even and uniform coating, as well as shortened processing times (see column 2 lines 65-66 and 73-75). Lopez teaches the method of introducing air into a coating composition to produce foam that is then sprayed onto the pharmaceutical solids (see example and column 3 line 72-column 4 line 9; instant claims 21 and 23).

The complete coverage of the drug particles is taught by Parikh et al., thus one of ordinary skill in the art at the time the invention was made would have found it obvious to modify their invention by using the foam coating technique of Lopez to help ensure that complete and uniform coverage of the particles could be achieved. The conversion of the coating mixture of Parikh et al. into a foam as taught by Lopez et al. results in a water based air foam. Continuation of the process taught by Parikh et al. yields agglomerated particles; thus the limitations of instant claim 21 are met by the foam coating method of Parikh et al. in view of Lopez. Therefore claims 21 and 23-26 are obvious over Parikh et al. in view of Lopez and as evidenced by Rudnic et al.

Claims 21-22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardie-Muncy et al. (previously cited) in view of Richardson et al. (previously cited)

Hardie-Muncy et al. teach the agglomeration of moisture sensitive particulate materials by whipping a coating medium into a foam then applying the foam to the particles so as to agglomerate and protect them from exposure to moisture (see abstract and column 1 lines 5-11). In particular, they teach that a binding agent is included at 0.1 to 20% in water to make up the foam composition (see column 2 lines 33-35; instant claim 26). Further, Hardie-Muncy et al. teach that their process forms a

foam by whipping air into the coating composition (water based air foam) then mixes in the particles to form agglomerates without atomizing the foam (see column 2 lines 46-57; instant claims 22 and 28). Hardie-Muncy et al. do not explicitly teach that the particles contain therapeutic or recite their size.

Richardson et al. teach hygroscopic (moisture sensitive) bioactive (therapeutic) components (see column 1 lines 7-11). These components are taught to be less than 1000 microns in diameter (see (column 8 lines 35-41; instant claim 21).

Since some bioactive particles are known to be sized less than 1000 microns and also to be moisture sensitive, based on Richardson et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to use such particles in the process taught by Hardie-Muncy et al. to protect them from undesired moisture and help them retain their desired structure and function. These agglomerated particles are capable of being utilized in a dosage form since they contain a drug (see instant claim 21). Therefore claims 21-22 and 26 are obvious over Hardie-Muncy et al. in view of Richardson et al.

Claims 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardie-Muncy et al. as evidenced by the Parsley reference (previously cited) and the Particle Size reference (previously cited).

Hardie-Muncy et al. teach the agglomeration of moisture sensitive particulate materials by foaming a coating medium then applying the foam to the particles so as to agglomerate and protect them from exposure to moisture (see abstract and column 1 lines 5-11; instant claim 21). In one example, a water based air foam is produced

utilizing gelatin as a binding agent (binder) in water and combined, without atomization, with a collection of bread particles (see column 2 lines 28-33 and example 1; instant claim 22). One subset of these particles (small bread particles) is taught to pass through a 14 US sieve size and be retained on a 50 US sieve size. The Particle Size reference teaches that a 14 US sieve size has openings that are 1.41mm in diameter while a 50 US sieve size has openings that are 297 μm in diameter. Thus this subset of particles must be between 297 and 1410 μm. The binding agent is included at 6.2% in the foam (as calculated by the examiner – see instant claim 26). In addition, parsley is included as a particulate ingredient in the agglomerate preparation. The Parsley reference teaches that this plant is known to have medicinal effects (e.g. therapeutic agent) (see paragraph 7; instant claim 21). The selection of any order of adding ingredients is prime facie obvious in the absence of new or unexpected results (see MPEP2144.04 IVc). Therefore the addition the particles on top of the foam or vice versa is obvious from the teachings of Hardie-Muncy et al. since no evidence is provided by the instant application of any unexpected result from one particular order of addition (see instant claims 23 and 27-28). Also, it would have been obvious to one of ordinary skill in the art to include a set of particles whose average size was less than 1000 μm, 750 μm or 500 μm as feed material for the agglomerates as a matter of routine experimentation given that the lower end of the acceptable size range for the small bread particles is 297 μm (see instant claims 21 and 24-25). As edible particles sized in a range known to be suitable for use in a dosage form, the agglomerated particles of Hardie-Muncy et al. as evidenced by the Parsley reference and the Particle Size reference are capable of being used in a dosage form (see instant claim 21). Therefore claims 21-28 are obvious over

Hardie-Muncy et al. as evidenced by the Parsley reference and the Particle Size reference.

Response to Arguments

Applicants' arguments and remarks filed May 19, 2010 have been fully considered.

The rejections detailed above address all of the pending claims. While the previous Office action did address the limitations of claim 27, the claim was not included in a statement of rejection. This inadvertent oversight has been corrected in the current action. Arguments concerning references cited in the rejections under 35 USC 103(a) are addressed and the Examiner's remarks concerning the declaration filed November 30, 2009 are reiterated.

Applicants' arguments regarding the teachings of Parikh et al. in the rejection made under 35 USC 103(a) over Parikh et al. in view of Lopez et al. as evidenced by Rudnic et al. are not persuasive. While applicants state that Parikh et al. does not relate to additional agglomerating beyond conventional techniques, the method of Parikh et al. in view of Lopez et al. as evidenced by Rudnic et al. teaches the formation of a therapeutic containing agglomerate product via the combination of a particles with an aqueous air foam that includes a binder. The method as claimed recites, "mixing the foam and powder to agglomerate the particles." Based on this recitation either the combination of the foam with the particles necessarily results in agglomeration of the particles or there are additional implicit steps that occur between the combination of the

foam with the particles and the formation of the agglomerates. In either situation, the teachings of Parikh et al. in view of Lopez et al. and Rudnic et al. meet these limitations.

Regarding declaration made under 37 CFR 1.132 and rejection under 35 USC 103(a):

While the insights provided by Dr. Kibbe are appreciated, they do not negate the teachings of Parikh et al. that recite the steps claimed in the instant application. Parikh et al. is concerned with the preparation of solid dosage forms that includes both the coating of particles and their granulation. Therefore there would have been good reason for one of ordinary skill in the art to look to other references concerned with coating technologies as well as granulation technologies to supplement the teachings of Parikh et al. "The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., In re Kahn, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)" (see MPEP 2144IV). Thus the prior art need not have the same motivation as applicants for performing the instantly claimed steps in order to still render them obvious. Also, the instant claims are drafted with open claim language, allowing the presence of intervening steps before the final product is reached. As Dr. Kibbe notes, granulation in this context refers to adhering numbers of particles together to make a granulate and Parikh et al. explicitly teach granulation of their particles to form them into tablets (see paragraphs 55 and 56). Therefore they teach the formation of agglomerated particles. In light of the supplementary teaches of Lopez about coating via an aqueous air foam and the motivation provided by Parikh et al. to uniformly coat

their particles, all the claimed steps are recited and the claimed agglomerated, therapeutic containing end result is obtained; thereby meeting the claim limitations. In addition Dr. Kibbe discusses attributes of the final product that are not supported by any data or evidence which are also not persuasive.

The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner
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